510(k) Summary

Seal Single-Use Biopsy Valve

December 5, 2013

1. **Company Identification**

EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Telephone: 678-708-4773
Fax: 678-567-8218
Establishment Registration: 300759133

2. **Contact Person**

Janna Babson
Regulatory Affairs Associate

3. **Device Name**

Commercial Name:	Seal Single-Use Biopsy Valve
Common/Usual Name:	Biopsy Valve
Classification Name:	Endoscopic, irrigation/suction system

4. **Device Classification**

Product Code:	OCX
Regulation Number:	876.1500
Class:	II
Review Panel:	Gastroenterology/Urology

5. **Intended Use:**

The Single-Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provide access for irrigation.

6. Device Description:

The Seal Single-Use Biopsy valve is provided non-sterile, and is composed of a cylindrical base and a connected cap. The Single-Use Biopsy Valve provides surgical instruments with sealable access to the working channel port of an endoscope. The valve consists of an attached cap and valve body with a circular opening. The cap is pre-perforated, and ensures instrument access and removal is tight and leak-free.

The valve is designed with a hollow body with a distal end that releasably attaches to the inlet port of the working channel. The valve body provides a flexible diaphragm seal that separates the body into a proximal chamber and distal chamber. The distal chamber secures onto the endoscope, while the proximal chamber secures the cap. Instruments are inserted through the cap and chambers, through the diaphragm seal, and into the endoscope. The diaphragm seal is configured such that a seal is formed due to deformation of the elastomer around an instrument when it is inserted through the opening, preventing fluids from passing through the biopsy valve.

The cap serves two primary functions. One function of the cap is to provide an additional seal around surgical instruments to prevent leakage. The second function is to allow modification of pressure during insufflation by opening the cap, allowing gasses to flow from the endoscope, and out of the biopsy valve.

7. Substantial Equivalence:

The device submitted for review is a modification of the Biopsy Valve (K111821). Changes to the device include a modification in material, and a change in dimensions. Both the modified and unmodified device is composed of thermoplastic elastomers. The modified device also has a reduction in overall height of the biopsy valve to provide an improved fit between the cap and body, as well as the valve to the instrument port.

The modified device is identical in terms of intended use, operating principle, performance, technology, energy used, and packaging.

Characteristic	Single-Use Biopsy Valve (Unmodified)	Single-Use Biopsy Valve (Modified)
510(k) number	K111821	Pending
Indications for Use	Biopsy valves are intended to provide access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from biopsy port throughout the endoscopic procedure, and provides access for irrigation.	Biopsy valves are intended to provide access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Characteristic	Single-Use Biopsy Valve (Unmodified)	Single-Use Biopsy Valve (Modified)
Material	Thermoplastic elastomer	Thermoplastic elastomer
Valve Inner Diameter	7 mm	7.1 mm
Endoscope compatibility	Olympus Fujinon EndoChoice Fuse	Olympus series 160, 180, and 190 endoscopes. Fujinon series 530, 590, and 600 endoscopes. EndoChoice Fuse endoscopes.
Removable cap with slit	Yes	Yes
Slit accommodate devices	Up to 3.2 mm	Up to 3.2 mm
Packaging	Individually packaged plastic pouch	Individually packaged plastic pouch
Performance testing:		
• 1 minute pressure test at 10 PSI – with device in biopsy valve	Pass	Pass
• 1 minute pressure test at 10 PSI – with device in biopsy valve	Pass	Pass
• 1 minute pressure test at 10 PSI after removing device from biopsy valve	Pass	Pass

8. **Non-Clinical Testing:**
The modified device has undergone both bench testing of performance and laboratory biocompatibility testing for cytotoxicity, sensitization, intracutaneous injection test, and system injection test, in accordance with 21 CFR, Part 58. The modified Single-Use Biopsy Valve results in no safety or efficacy concerns regarding biocompatibility or performance. Likewise, in conformance with 21 CFR 807.92(b)(3), the modified device performs as well as the predicate in all testing performed.

9. **Conclusion:**
   The modified Single-Use Biopsy Valve is substantially equivalent to the unmodified predicate device listed above in performance, technical characteristics, biocompatibility, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2014

EndoChoice, Inc.
Janna Babson
Regulatory Affairs Associate
11810 Wills Road
Alpharetta, GA 30009

Re: K133734
Trade/Device Name: Biopsy Valve
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: February 21, 2014
Received: February 24, 2014

Dear Janna Babson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133734

Device Name
Single-Use Biopsy Valve

Indications for Use *(Describe)*

The Single-Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from biopsy port throughout the endoscopic procedure, and provides access for irrigation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.03.19 09:00:05 -04'00'

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